# BÜHLMANN fCAL® turbo

Immuno turbidimetric fecal CALPROTECTIN Assay

**Automation**

**Speed**

**Simple stool preparation**

## Automated fecal Calprotectin results

- Streamlined Workflow & Random Access
- Full integration into your Routine Work

## Fecal Sample Preparation with CALEX® Cap

- Hassle free pre-Analytics
- Fully compatible with Total Laboratory Automation

## Use the established reference

- Proven & stable Standardization
- Established & Validated Cut-off in IBD Diagnosis

**BÜHLMANN fCAL® turbo is FDA 510(k) cleared (K190784). For *in vitro* Diagnostic Use.**

**CALEX® Cap: FDA 510(k) cleared (K191718 & 232057). For *in vitro* Diagnostic Use.**

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MF059ML-09 EUS

# Fecal Calprotectin in 10 minutes

BÜHLMANN fCAL® turbo, a groundbreaking turbidimetric immunoassay, offers rapid calprotectin quantification. Compatible with most clinical chemistry analyzers, this technology allows flexible random-access use, perfect for high-throughput routines. The fCAL turbo significantly reduces hands-on time, ensuring swift reporting of calprotectin results from human stool samples.

Centrifuged stool samples from BÜHLMANN's CALEX® Cap can be applied directly to your existing analyzer, requiring no special equipment. The results, spanning 30 to 10,000 µg/g, takes only ten minutes, with automatic re-testing for highly concentrated samples.

| | | |
|---|---|---|
| Available application notes | Siemens | Advia 1650/1800, Advia 2400, Advia XPT, Atellica CH 930 |
| | Roche | Cobas c501/c502, Cobas c701/c702, Cobas Pro c503, Cobas Pure c303 |
| | Abbott | Architect (c series), Alinity |
| | Beckman | AU series (AU400/640), AU480, AU680, AU5800, DxC 700 AU, DxC 600/800 |
| | Mindray | BS-200E, BS-240/ 240 Pro, BS-380, BS-400 |
| | Thermo Fisher | Konelab30i, Indiko/Indiko Plus |
| | Ortho | Vitros 5600 |
| | The Binding Site | Optilite |
| | Horiba ABX | Pentra 400 |
| | BioSystems | BA200 |

The analyzers mentioned in the above table are registered trademarks held by the corresponding manufactures.

| PRODUCT DESCRIPTION | |
|---|---|
| Method | Particle-enhanced turbidimetric immunoassay (PETIA) |
| Sample Type | CALEX® Cap prepared stool sample |
| Kit Format | 2 reagents (wedge bottles for direct loading on some platforms)<br>Reagents last for ~200 tests (platform dependent) |
| Sample Preparation | CALEX® Cap stool sample can be used directly without additional dilution |
| Reagent on board | Stable for at least 60 days |
| Calibration | Stable for up to 60 days |
| Calibration range | 0-2000 µg/g |
| Measuring range | 30-10,000 µg/g |
| Sample volume | ~10 µL centrifuged fecal Extract (1:500) |
| Time to First Result | 10 min<br>CALEX® stool preparation ~20 min |

## Stool Samples on Clin Chem Platforms

Centrifuged CALEX® prepared stool samples are devoid of undigested dietary fibers, reducing bacterial load by ~95%, comparable to routine urine samples from UTI patients.

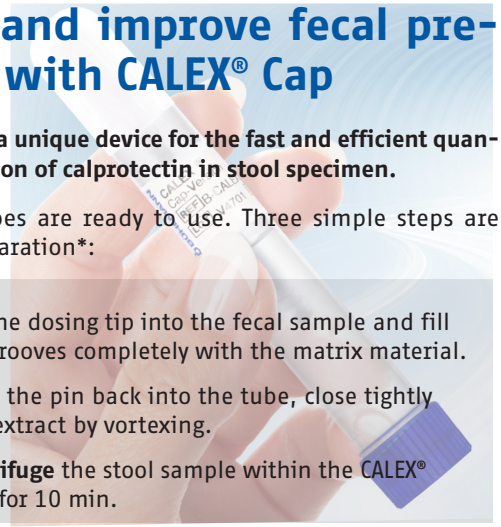
Minimal carry-over effects (<0.5%) on high-throughput analyzers have been confirmed, excluding serum contaminations.

Turbidimetric reagents lack critical compounds, making interactions with other assays highly unlikely and unobserved.

# Simplify and improve fecal preparation with CALEX® Cap

**The CALEX® Cap is a unique device for the fast and efficient quantitative preparation of calprotectin in stool specimen.**

The prefilled tubes are ready to use. Three simple steps are required for preparation*:



**STEP 1** **Dip** the dosing tip into the fecal sample and fill the grooves completely with the matrix material.

**STEP 2** **Place** the pin back into the tube, close tightly and extract by vortexing.

**STEP 3** **Centrifuge** the stool sample within the CALEX® tube for 10 min.

The prepared stool sample (1:500) is ready to use in the turbidimetric assay. The CALEX® Cap preparation highly correlates with the manual weighing method.

*Please see the full instructions for use (IFU) on buhlmannlabs.com for more detailed information prior to use

# Use the established reference

**BÜHLMANN fCAL® turbo standardization is based on the gold standard BÜHLMANN fCAL® ELISA, implemented globally in laboratories.**

- **A trustful stable standardization of calprotectin**

  Our long experience with the complex protein and our large network in science and clinics guarantee a continuous quality of the assay.

- **Established cut-off for diagnosis and monitoring**

  Based on clinical experience over 10 years and clinical studies. Application of a cut-off **80 µg/g** means higher specificity with minor reduction in sensitivity facilitating the diagnosis of IBD with a major improvement of cost effectiveness. To keep the indecisive grey zone to a minimum, cut-off **160 µg/g** shows an ideal trade-off for a combination of specificity and better sensitivity for the studied patient cohort.

- **Clinically proven in more than 100 publications**

  Please, refer to our homepage or ask for reference literature.

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**BÜHLMANN fCAL® turbo Ordering Codes:**

| | | |
|---|---|---|
| Reagent Kit (~200 tests) | B-KCAL-RSET-US | R1 35 mL, R2 7 mL |
| Calibrator Kit | B-KCAL-CASET | 6 levels, 1 mL each; Ready to use |
| Control Kit | B-KCAL-CONSET | 3 x 2 levels, 1 mL each; Ready to use |

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